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# NEWS RELEASE

# Judd Gregg

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**FOR IMMEDIATE RELEASE:**

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## **Chairman Gregg Statement on Committee Approved Health Bills**

**Washington, DC** - Today the Senate Committee on Health, Education, Labor and Pensions unanimously approved a series of health-related bills. The HELP Committee also unanimously approved a long list of nominees for posts throughout the federal government. Chairman Gregg made the following statement:

“The HELP Committee approved a number of important bills, each related to the health of our nation. The Food Allergen Labeling and Consumer Protection Act will provide reliable, accurate, and clear allergen information to the 7 million children and adults with food allergies who face serious, even potentially deadly, risks because of ingredients with allergic potential. Simply stated, this bill has the potential to save the lives of children. The Minor Use and Minor Species Health Act helps ensure the health of our animal population by addressing the critical shortage of approved animal drugs for minor species and for minor uses in major species. The Mammography Quality Standards Reauthorization Act continues an important program that has helped save the lives of many women. The Medical Device Technical Corrections Act makes much needed technical changes to the Medical Device User Fee and Modernization Act. And finally, the Organ Donation and Recovery Improvement Act encourages organ donation and increases public awareness regarding donations,” said Gregg.

“There has been a cumulative impasse on these five important issues for thirteen and a half years. I applaud HELP Committee members for working together in a bipartisan manner to break the stalemate and approve these bills today. I encourage the Senate to act quickly on each of them,” said Gregg.

### **Bills Agreed To:**

**S. 1879, Mammography Quality Standards Reauthorization Act of 2003**

**S. 1881, Medical Device Technical Corrections Act of 2003**

**S.741, Minor Use and Minor Species Animal Health Act of 2003 and Food Allergen Labeling**

**and Consumer Protection Act of 2003**

**S. 573, Organ Donation and Recovery Improvement Act**

(bill summaries below)

**Nominations Agreed To:**

**National Commission on Libraries and Information Science**

Jose Aponte  
Sandra Ashworth  
Edward Bertorelli  
Carol Diehl  
Allison Druin  
Beth Fitzsimmons  
Patricia Hines  
Colleen Huebner  
Stephen Kennedy  
Bridget Lamont  
Mary Perdue  
Herman Totten

**Corporation for National and Community Service**

David Eisner  
Carol Kinsley

**Department of Education**

Raymond Simon

**National Mediation Board**

Read Van de Water

**James Madison Foundation**

Drew McCoy

**National Council on the Arts**

James McBride

**U.S. Institute of Peace**

Laurie S. Fulton  
John West

**Department of Education**

Susan Sclafani

**Department of Labor**

Stephen Law

**Public Health Service - 174 nominees**

### **Bill Summaries**

#### **S. 1879, Mammography Quality Standards Reauthorization Act of 2003**

Amends the Public Health Service Act to extend funding for the mammography facilities certification program through FY 2005.

Permits the Secretary of Health and Human Services to issue two additional types of certificates that are necessary to avoid possible delays in providing mammography services and the diagnosis and treatment of breast cancer.

A temporary renewal certificate may be issued to the facilities seeking reaccreditation that have been awarded and accreditation extension for specified reasons - including inability of the accrediting body to complete the process in time - but do not compromise the quality of mammography.

A provisional certificate may be issued upon the request of an accreditation body to enable the facility to conduct examinations for educational purposes during an onsite visit by the accreditation body.

#### **S. 1881, Medical Device Technical Corrections Act of 2003**

The Medical Devices Technical Corrections Act clarifies original congressional intent and allows for smooth implementation of those changes. It better aligns written intent with current practice. The bill clarifies the application of third party inspections.

#### **S. 741, Minor Use and Minor Species Animal Health Act of 2003 and Food Allergen Labeling and Consumer Protection Act of 2003**

The Minor Use Minor Species Animal Health Act is intended to address the critical shortage of approved animal drugs for minor species (species other than cattle, horses, swine, chickens, turkeys, dogs, and cats) and for minor uses in major species (a rare disease in a major species). The bill establishes two new ways to lawfully market new animal drugs, while ensuring appropriate safeguards for animal and human health.

First, it establishes a conditional approval mechanism for such drugs as long as they are proven safe and demonstrate a reasonable expectation (rather than substantial evidence) of effectiveness. This would allow sponsors to recoup some development costs through marketing of the product prior to full, unconditional approval.

Second, it creates an index of legally marketed unapproved new animal drugs for some minor species. FDA would include a new animal drug in the index only if it is deemed safe and the benefits of using the drug outweigh the risks. The index is intended to provide a way to lawfully market those minor species drugs for which there is unlikely to be sufficient financial incentive to seek a full or conditional approval. Additionally, sponsors would receive 7 years of marketing exclusivity for any approved new animal drug or new use.

The Food Allergen Labeling and Consumer Protection Act of 2003 is intended to establish plain

language labeling of allergenic substances in food to enable the 7 million children and adults with food allergies to avoid products containing ingredients to which they are allergic.

Requires manufacturers to label the presence of the major eight allergens (i.e., milk, eggs, soy, peanuts, tree nuts, wheat, fish, and shellfish) in foods. These eight foods account for 90% of food allergies.

Permits manufacturers to choose between two labeling paradigms. Food products must be labeled under either of the paradigms by January 1, 2006.

Requires the Secretary to publish national data on the prevalence of food allergies and the incidence of deaths and injuries.

To assist those with celiac disease to avoid foods containing glutens, the bill requires the Secretary to define “gluten free” as a voluntary claim for food products.

### **S. 573, Organ Donation and Recovery Improvement Act (Frist Substitute)**

Amends the Public Health Service Act to create a reimbursement of travel subsistence for living donors and to increase public awareness and grant programs to encourage organ donation through FY 2008.

Provides reimbursement of travel for living donors up to (\$5M for 5 years)

Creates grant programs to increase organ donation (\$15M for FY 2004)

Creates grant programs to place organ donation coordinators in hospitals (\$3M for FY 2004)

Includes HHS study on organ procurement (\$2M for FY 2004)

Authorizes HHS Report on organ donation issues

Creates a registry to monitor the long term health of living donors

Supports a study of the ethical implications of a proposal to increase cadaveric donation.

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